

Docket No. GZ-210100

**Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a)):**

[X] Pursuant to 37 C.F.R. § 1.8(a), I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Commissioner for Patents, Washington D.C. 20231.

Dated: September 24, 2001

Name of Person Certifying: Peggy Nichols

Printed Name: Peggy Nichols

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Charles A. Nicolette

Assignee: Genzyme Corp.

Filing Date: May 30, 2001

Examiner: Unassigned

Serial No.: 09/870,216

Group Art Unit: 1653

Title: THERAPEUTIC COMPOUNDS FOR OVARIAN CANCER

Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

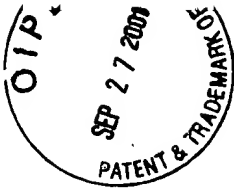
Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

**I. Timing of the Information Disclosure Statement:**

This Information Disclosure Statement is filed:

- ☐ With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).
- ☐ Within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 C.F.R. § 1.491.
- ☒ Before the mailing date of a first Office action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for any fees required pursuant to 37 C.F.R. §§ 1.17(p) or 1.17(i)(1).



This Information Disclosure Statement is filed:

- ☐ After the first Office Action and more than three months after the application's filing date; or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first, and the Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for the fee (\$180) set forth in 37 C.F.R. § 1.17(p) and any additional required fees.

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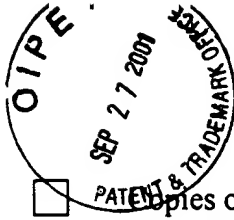
- ☐ After the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$180.00) set forth in 37 C.F.R. § 1.17(i)(1) and a certification as specified in 37 C.F.R. § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.

The undersigned certifies that:

- ☐ Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

## II. Copies of the Cited Items:

- ☒ Copies of all of the items listed on the attached Form PTO-1449 are enclosed.
- ☐ Copies of only the following items listed on the attached Form PTO-1449 are enclosed: \_\_\_\_\_.
- ☐ Copies of those items which are marked with an asterisk (\*) in the attached Form PTO-1499 are not supplied because they were previously cited by or submitted to the Patent Office in a prior Application No. \_\_\_\_\_, filed \_\_\_\_\_ and relied upon in this application for an earlier filing date under 35 U.S.C § 120. See 37 C.F.R. § 1.98(d).



PATENT

copies of those items which are marked with an asterisk (\*\*) in the attached Form PTO-1499 were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.

### III. Concise Explanation of Relevance:



A concise explanation of relevance of the items listed on Form PTO-1449 is not given.



A concise explanation of relevance of [some of] the items listed on Form PTO-1449 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references (copy attached).

### IV. Conclusion:

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.

The Commissioner is hereby authorized to charge Deposit Account No. 50-1189 Docket No.: 19442-7216 for any additional fees required in connection with the filing of this Information Disclosure Statement.

DATE:

Sept. 24, 2001

Respectfully submitted,

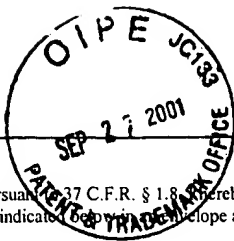
By:

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Applicant: Charles A. Nicolette      Assignee: Genzyme Corp.  
Filing Date: May 30, 2001      Examiner: Unassigned  
Serial No.: 09/870,216      Group Art Unit: 1653  
Title: THERAPEUTIC COMPOUNDS FOR OVARIAN CANCER

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09/28/2001 CCHAU1 00000002 501189 09870216

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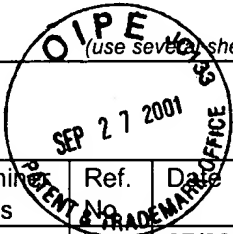
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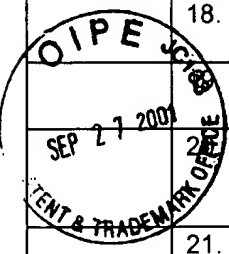
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Respectfully submitted,

By: Antoinette F. Konski  
Antoinette F. Konski  
Registration No.: 34,202

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Form PTO-1449			Docket No. GZ-210100		Appl. No. 09/870,216		
INFORMATION DISCLOSURE STATEMENT			Applicant(s)  Charles A. NICOLETTE				
 (use several sheets if necessary)			Filing Date: May 30, 2001		Group Art Unit: 1653		
			U.S. PATENT DOCUMENTS				
Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date (if appropriate)
	1.	07/28/87	4,683,195	Mullis et al.			
	2.	07/28/87	4,683,202	Mullis			
	3.	06/28/88	4,754,065	Levenson et al.			
	4.	01/24/89	4,800,159	Mullis et al.			
	5.	08/08/95	5,440,013	Kahn			
	6.	11/17/98	5,837,249	Heber-Katz et al.			
FOREIGN PATENT DOCUMENTS							
Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Translation YES NO
	7.	08/01/96	WO 96/23060	The Government of the United States of America			
OTHER DOCUMENTS <i>(including author, title, date, pertinent pages, etc.)</i>							
Examiner Initials	Ref. No.	Title					
	8.	Altman, J.D. et al., "Phenotypic analysis of antigen-specific T lymphocytes" (1996) <i>Science</i> <b>274</b> (5284):94-96					
	9.	Bertoni, R. et al., "Human class I supertypes and CTL repertoires extend to chimpanzees" (1998) <i>J. Immunol.</i> <b>161</b> :4447-4455					
	10.	Boczkowski, D. et al., "Dendritic cells pulsed with RNA are potent antigen-presenting cells in vitro and in vivo" (1996) <i>J. Exp. Med.</i> <b>184</b> :465-472					
	11.	Bordignon, C. et al., "Retroviral vector-mediated high-efficiency expression of adenosine deaminase (ADA) in hematopoietic long-term cultures of ADA-deficient marrow cells" (1989) <i>PNAS USA</i> <b>86</b> :6748-6752					
	12.	Carter, B.J., "Adeno-associated virus vectors" (1992) <i>Curr. Op. Biotechnol.</i> <b>3</b> :533-539					
	13.	Caruso, A. et al., "Flow cytometric analysis of activation markers on stimulated T cells and their correlation with cell proliferation" (1997) <i>Cytometry</i> <b>27</b> :71-76					
	14.	Correll, P.H. et al., "Production of human glucocerebrosidase in mice after retroviral gene transfer into multipotential hematopoietic progenitor cells" (1989) <i>PNAS USA</i> <b>86</b> :8912-8916					
	15.	Coulie, P.G., "Human tumour antigens recognized by T cells: new perspectives for anti-cancer vaccines?" (1997) <i>Molec. Med. Today</i> <b>3</b> :261-268					
	16.	Culver, K. et al., "Lymphocytes as cellular vehicles for gene therapy in mouse and man" (1991) <i>PNAS USA</i> <b>88</b> :3155-3159					
	17.	Dharanipragada, R. et al., "The absolute configuration of an intermediate in the asymmetric synthesis of unusual amino acids" (1992) <i>Acta. Cryst.</i> <b>C48</b> :1239-1241					
EXAMINER:				DATE CONSIDERED:			
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	18.	Dharanipragada, R. et al., "Synthetic linear and cyclic glucagon antagonists" (1993) <i>Int. J. Peptide Protein Res.</i> <b>42(1)</b> :68-77	
		DiMaio, J. et al., "Synthesis of chiral piperazin-2-ones as model peptidomimetics" (1989) <i>J. Chem. Soc. Perkin Trans.</i> <b>1(9)</b> :1687-1689	
	20.	Feltkamp, M.C.W. et al., "Competition inhibition of cytotoxic T-lymphocyte (CTL) lysis, a more sensitive method to identify candidate CTL epitopes than induction of antibody-detected MHC class I stabilization" (1995) <i>Immunol. Lett.</i> <b>47</b> :1-8	
	21.	Ferguson, et al. "Cell-surface anchoring of proteins via glycosyl-phosphatidylinositol structures" (1988) <i>Ann. Rev. Biochem.</i> <b>57</b> :285-320	
	22.	Fujihashi, K. et al., "Cytokine-specific ELISPOT assay single cell analysis of IL-2, IL-4 and IL-6 producing cells" (1993) <i>J. Immunol. Meth.</i> <b>160</b> :181-189	
	23.	Garvey D.S. et al., "3,4-disubstituted $\gamma$ -lactam rings as conformationally constrained mimics of peptide derivatives containing aspartic acid or norleucine" (1990) <i>J. Org. Chem.</i> <b>55(3)</b> :936-940	
	24.	Hruby, V.J., "Conformational restrictions of biologically active peptides via amino acid side chain groups" (1982) <i>Life Sciences</i> <b>31</b> :189-199	
	25.	Hruby, V.J. et al. "Emerging approaches in the molecular design of receptor-selective peptide ligands: conformational, topographical and dynamic considerations" (1990) <i>Biochem J.</i> <b>268</b> :249-262	
	26.	Isakov, N. et al., "ZAP-70 binding specificity to T cell receptor tyrosine-based activation motifs: The tandem SH2 domains of ZAP-70 bind distinct tyrosine-based activation motifs with varying affinity" (1995) <i>J. Exp. Med.</i> <b>181</b> :375-380	
	27.	Jones, R.C.F. and G.J. Ward, "Amide bond isosteres: imidazolines in pseudopeptide chemistry" (1988) <i>Tetrahedron Lett.</i> <b>29(31)</b> :3853-3856	
	28.	Kahn, M. and S. Bertenshaw, "The incorporation of $\beta$ -turn prosthetic units into merrifield solid phase peptide synthesis" (1989) <i>Tetrahedron Lett.</i> <b>30(18)</b> :2317-2320	
	29.	Karlsson, S. et al., "Stable gene transfer and tissue-specific expression of a human globin gene using adenoviral vectors" (1986) <i>The EMBO J.</i> <b>5(9)</b> :2377-2385	
	30.	Kawakami, Y. et al., "Cloning of the gene coding for a shared human melanoma antigen recognized by autologous T cells infiltrating into tumor" (1994) <i>PNAS USA</i> <b>91(9)</b> :3515-3519	
	31.	Kazmierski, W. M. and V.J. Hruby, "Asymmetric synthesis of topographically constrained amino acids: synthesis of the optically pure isomers of $\alpha,\beta$ -dimethyl-phenylalanine and $\alpha,\beta$ -dimethyl-1,2,3,4-tetrahydroisoquinoline-3-carboxylic acid" (1991) <i>Tetrahedron Lett.</i> <b>32(41)</b> :5769-5772	
	32.	Kazmierski, W.M. et al., "Topographic design of peptide neurotransmitters and hormones on stable backbone templates: relation of conformation and dynamics to bioactivity" (1991) <i>J. Am. Chem. Soc.</i> <b>113</b> :2275-2283	
	33.	Kemp, D.S. and P.E. McNamara, "Conformationally restricted cyclic nonapeptides derived from L-cysteine and LL-3-amino-2-piperidone-6-carboxylic acid (LL-Acp), a potent $\beta$ -turn-inducing dipeptide analogue" (1985) <i>J. Org. Chem.</i> <b>50</b> :5834-5838	
	34.	Kemp, D.S. and B.R. Bowen, "Conformational analysis of peptide-functionalized diacylaminoepindolidiones $^1\text{H}$ NMR evidence for $\beta$ -sheet formation" (1988) <i>Tetrahedron Lett.</i> <b>29(40)</b> :5081-5082	
	35.	Kemp, D.S. and W.E. Stites, "A convenient preparation of derivatives of 3(S)-amino-10(R)-carboxy-1, 6-diaza-cyclodeca-2, 7-dione The dilactam of L- $\alpha$ , $\gamma$ -diaminobutyric acid and D-glutamic acid: A $\beta$ -turn template" (1988) <i>Tetrahedron Lett.</i> <b>29(40)</b> :5057-5060	

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INFORMATION DISCLOSURE STATEMENT		Applicant(s) Charles A. NICOLETTE	
(use several sheets if necessary)		Filing Date: May 30, 2001	Group Art Unit: 1653
36.	Kemp, D.S. and T.P. Curran, "(2, 5S, 8S, 11S)-1-acetyl-1, 4-diaza-3-keto-5-carboxy-10-thia-tricyclo-[2.8.0 <sup>4,8</sup> ]-ridecane, 1 the preferred conformation of 1 (1= $\alpha$ temp-OH) and its peptide conjugates $\alpha$ temp-L-(Ala) <sub>n</sub> -OR (n=1 to 4) and $\alpha$ -temp -L-Ala-L-Phe-Lys( $\epsilon$ Boc)-L-Lys( $\epsilon$ -Boc)-NHMe studies of templates for $\alpha$ -helix formation" (1988) <i>Tetrahedron Lett.</i> <b>29(39)</b> :4935-4938		
	Kemp, D.S. and J.S. Carter, "Amino acid derivatives that stabilize secondary structures of polypeptides. 4. Practical synthesis of 4-(alkylamino)-3-cyano-6-azabicyclo[3.2.1]oct-3-enes (ben derivatives) as $\gamma$ -turn templates" (1989) <i>J. Org. Chem.</i> <b>54</b> :109-115		
38.	McGrory, W.J. et al., "Short communications: A simple technique for the rescue of early region I mutation into infectious human adenovirus type 5" (1988) <i>Virology</i> <b>163</b> :614-617		
39.	Merrifield, R.B., "New approaches to the chemical synthesis of peptides" (1967) <i>Recent Progress in Hormone Res.</i> <b>23</b> :451-482		
40.	Miyake, A. et al., "Synthesis and angiotensin converting enzyme inhibitory activity of 1,2,3,4-tetrahydroisoquinoline-3-carboxylic acid derivatives" (1984) <i>J. Takeda Res. Labs.</i> <b>43(3/4)</b> :53-76		
41.	Mosier, D.E. et al., "Resistance to human immunodeficiency virus 1 infection of SCID mice reconstituted with peripheral blood leukocytes from donors vaccinated with vaccinia gp160 and recombinant gp160" (1993) <i>PNAS. USA</i> <b>90</b> :2443-2447		
42.	Muzyczka, "Use of adeno-associated virus as a general transduction vector for mammalian cells" (1992) <i>Curr. Top. Microbiol. Immunol.</i> <b>158</b> :97-129		
43.	Nagai, U. and K. Sato, "Synthesis of a bicyclic dipeptide with the shape of $\beta$ -turn central part" (1985) <i>Tetrahedron Lett.</i> <b>26(5)</b> :647-650		
44.	Nair, S. et al., "Soluble proteins delivered to dendritic cells via pH-sensitive liposomes induce primary cytotoxic T lymphocyte responses in vitro" (1992) <i>J. Exp. Med.</i> <b>175</b> :609-612		
45.	Olson, G.L. et al., "Design and synthesis of a protein $\beta$ -turn mimetic" (1990) <i>J. Am. Chem. Soc.</i> <b>112</b> :323-333		
46.	Paglia, P. et al., "Murine dendritic cells loaded in vitro with soluble protein prime cytotoxic T lymphocytes against tumor antigen in vivo" (1996) <i>J. Exp. Med.</i> <b>183</b> :317-322		
47.	Pardoll, D.M., "Cancer vaccines" (1998) <i>Nature Med.</i> <b>4(5 Suppl.)</b> :525-531		
48.	Parker, et al., "Sequence motifs important for peptide binding to the human MHC class I molecule, HLA-A2" (1992) <i>J. Immunol.</i> <b>149(11)</b> :3580-3587		
49.	Parker, K.C. et al. (1995) "Peptide Binding to MHC Class I Molecules: Implications for Antigenic Peptide Prediction" <i>Immunol. Res.</i> <b>14</b> :34-57		
50.	Parkhurst, M.R. et al., "Improved induction of melanoma-reactive CTL with peptides from the melanoma antigen gp100 modified at HLA-A*0201-binding residues" (1996) <i>J. Immunol.</i> <b>157</b> :2539-2548		
51.	al-Ramadi, B.K. et al., "Lack of strict correlation of functional sensitization with the apparent affinity of MHC/peptide complexes for the TCR" (1992) <i>J. Immunol.</i> <b>155(2)</b> :662-673		
52.	Rill, D.R. et al., "An approach for the analysis of relapse and marrow reconstitution after autologous marrow transplantation using retrovirus-mediated gene transfer" (1992) <i>Blood</i> <b>79(10)</b> :2694-2700		
53.	Rouse, R.J.D. et al., "Induction in vitro of primary cytotoxic T-lymphocyte responses with DNA encoding herpes simplex virus proteins" (1994) <i>J. Virol.</i> <b>68(9)</b> :5685-5689		
54.	Salazar, E. et al., "Agonist peptide from a cytotoxic T-lymphocyte epitope of human carcinoembryonic antigen stimulates production of TC1-type cytokines and increases tyrosine phosphorylation more efficiently than cognate peptide" (2000) <i>Int. J. Cancer</i> <b>85</b> :829-838		
55.	Samanen, J. et al., "5,5-dimethylthiazolidine-4-carboxylic acid (DTC) as a proline analog with restricted		
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		conformation" (1990) <i>Int. J. Peptide Protein Res.</i> <b>35</b> :501-509	
	56.	Schlesinger, S. and T.W. Dubensky, Jr., "Alphavirus vectors for gene expression and vaccines" (1999) <i>Curr Opin Biotechnol.</i> <b>10</b> (5):434-439	
		Sette, A. et al., "The relationship between class I binding affinity and immunogenicity of potential cytotoxic T cell epitopes" (1994) <i>J. Immunol.</i> <b>153</b> (12):5586-5592	
	57.	Shirai, M. et al., "CTL responses of HLA-A2.1-transgenic mice specific for hepatitis C viral peptides predict epitopes for CTL of humans carrying HLA-A2.1" (1995) <i>J. Immunol.</i> <b>154</b> :2733-2742	
	59.	Stuber, G. et al., "HLA-A0201 and HLA-B7 binding peptides in the EBV-encoded EBNA-1, EBNA-2 and BZLF-1 proteins detected in the MHC class 1 stabilization assay. Low proportion of binding motifs for several HLA class 1 alleles in EBNA-1" (1995) <i>Int. Immunol.</i> <b>7</b> (4):653-663	
	60.	Tan, L. et al., "An improved assembly assay for peptide binding to HLA-B*2705 and H-2K*class I MHC molecules" (1997) <i>J. Immunol. Meth.</i> <b>209</b> (1):25-36	
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## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date (if appropriate)
	1.	07/28/87	4,683,195	Mullis et al.			
	2.	07/28/87	4,683,202	Mullis			
	3.	06/28/88	4,754,065	Levenson et al.			
	4.	01/24/89	4,800,159	Mullis et al.			
	5.	08/08/95	5,440,013	Kahn			
	6.	11/17/98	5,837,249	Heber-Katz et al.			

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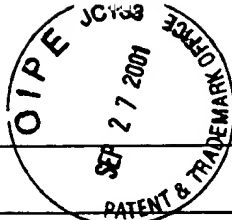
Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Translation YES NO
	7.	08/01/96	WO 96/23060	The Government of the United States of America			

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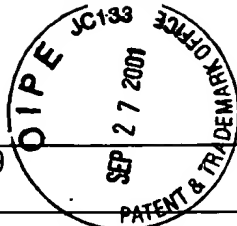
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